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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,022	10/10/2003	Paul O. Zamora	30817-1012	5302

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,022	ZAMORA, PAUL O.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

The instant application is filed as a continuation-in-part. It appears that only claims 4-7, 12, 21, 22, 25-28 and 34-42 are fully supported by the parent, S. N. 10/450,309 (now US 6,921,811). The remaining claims, 1-3, 8-11, 13-20, 23, 24 and 29-33, are not fully supported by the parent or entitled to the priority date of the parent.

Applicant's arguments filed August 1, 2006 have been fully considered but they are not persuasive.

Applicant contends that "Hydrophobic complex such as heparin bound by hydrophobic interaction is described in 10/450,309 at column 62-67." This passage describing the complex states "A growth factor molecule may be adsorbed onto the heparin surface of a silyl-heparin complex bound by hydrophobic interaction to a contacting surface of a medical device." It is not the heparin, per se, but the *silyl*-heparin that is involved in the hydrophobic interaction, with the silyl presumably being the business end of the molecule with respect to this interaction. This silyl moiety does not provide adequate written description for any generic hydrophobic prosthetic moiety recited in claim 1.

Regarding "polyanions," Applicant states "Polyanion is known as heparin and heparin-activity molecule and is found in the abstract of 10/450,309." This would be support is the polyanion of claim 1 were limited to what is described in '309 as "heparin and heparin-activity molecules." This is clearly not the case, as indicated by claim 3. '309 describes "heparin" as follows: "'Heparin' as used herein includes complex carbohydrates or mimetics of complex

carbohydrates with properties similar to those of heparin, including heparin sulfate, hyaluronic acid, etc." This does not support the infinitely broader genus of "polyanions." The examiner fails to see how one of ordinary skill would extrapolate that definition to a genus comprising species such as polyacrylic acid or collagen, for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8-10, 13, 14, 16 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Zamora et al (WO 02/10221).

Applicant notes that the instant application is supported by provisional application S. N. 60/418,127, filed 10/10/02, so that Zamora, published 2/7/02 does not qualify as 102(b) art. This is correct. The reference is 102(a) art.

Zamora discloses a variety of polymeric films, including polyester, polyurethane and polylactide/polyglycolide, complexed with a construct comprising the polyanion, heparin, covalently attached to a hydrophobic benzyl-(1,2-dimethyl)disilyl moiety and further complexed with the fibroblast growth factor, fibronectin. See examples. The hydrophobic moiety renders the heparin amphiphilic and allows for the complexation with the polymeric film. Although the product thus prepared is not specifically called a "wound dressing," it comprises the required components of the recited instantly recited product and therefore anticipates the claims.

Claim Rejections - 35 USC § 103

Claims 1-3, 8-11, 13, 14, 16, 20, 23, 24 and 29-33 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al (WO 02/10221).

Applicant's arguments filed August 1, 2006 have been fully considered but they are not persuasive. Applicant's only argument is that Zamora is not an effective 103(a) reference. As noted above, it is a proper 102(a) reference and is therefore also a proper reference under 103(a).

Zamora teaches as set forth above. As noted above, the product prepared in the examples is not specifically called a "wound dressing" or exemplify all the embodiments recited in the claims. However, the reference does expressly suggest the use of the prepared composite products as wound dressings. See the paragraph bridging pages 16 and 17. In addition to the exemplified heparin as the polyanion, the reference further teaches the use of other "heparin-activity" molecules. See abstract and page 9, last paragraph. The reference further teaches a variety of bioactive/therapeutic molecules, as well as their use in combination. See pages 9 and 10, 1st paragraph on each page and page 26, last paragraph. Finally, the reference teaches a variety of polymeric films that have utility in preparing the wound dressings. See page 17, beginning at line 17, and continuing through page 18, line 9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the exemplified products using the various suggested components (polyanions, bioactive/therapeutic molecules, polymeric films) for the preparation of wound dressings. One of ordinary skill would reasonably expect success in doing so because the reference had taught that these products had this utility. In the absence of unexpected results, it would be within the scope of the artisan to prepare these suggested products through routine

experimentation. There is no demonstration of criticality in any particular component. It would be further obvious for one of ordinary skill to apply said products to a wound for treatment of said wound.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al (WO 02/10221) as applied to claims 1, 3, 8-11, 13, 14, 16, 20, 23, 24 and 29-33 above, and further in view of either of (1) Byun et al (US 6,245,753) or (2) Ishihara et al (Biomed. Mater. Res., 2000).

Applicant's arguments filed August 1, 2006 have been fully considered but they are not persuasive. Applicant's only argument is that Zamora is not an effective 103(a) reference. As noted above, it is a proper 102(a) reference and is therefore also a proper reference under 103(a).

Zamora teaches as set forth above. The reference does not teach the full scope of hydrophobic moieties recited in claim 2.

Byun teaches the preparation of amphiphilic heparin derivatives by the covalent attachment of a variety of hydrophobic agents. See col 2, lines 29-58. The reference further teaches that the modified heparin has utility as a coating material for medical devices.

Ishihara teaches that polystyrene has utility for the attachment of heparin to a polymeric surface to deliver heparin-binding growth factors and stimulate epithelial cell growth. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the silyl moiety in the Zamora product with any agent known to be useful for rendering heparin amphiphilic, such as those taught by Byun or Ishihara. One of ordinary skill would reasonably expect success in such a modification because Byun expressly

suggests similar utilities as those taught by Zamora and a similar teaching by Ishihara. There has been no criticality demonstrated with any particular hydrophobic moiety.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al (WO 02/10221) as applied to claims 1, 2, 8-11, 13, 14, 16, 20, 23, 24 and 29-33 above, and further in view of Cima et al (US 5,906,828).

This rejection is not addressed.

Zamora teaches as set forth above. The reference does not teach the full scope of polyanions recited in claim 3.

Cima teaches that a variety of polymeric materials, including polyacrylates, collagen, glycosaminoglycans, (essentially the same group of polysaccharides as "heparin-activity molecules" as defined by Applicant) and alginate have utility as substrates as tethers for attaching growth effector molecules to the surface of a medical device, similar to the function of heparin in Zamora. See col 5-6. The thus prepared growth effector molecule tethered compositions can be used in the form of wound dressings. See paragraph bridging col 9-10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the polyanionic materials taught by Cima for the heparin-activity molecule in the Zamora composition. One of ordinary skill would reasonably expect success in making this modification because had Cima had taught these polymers as functional equivalents of heparin-like molecules in the attachment of growth effector molecules to the surface of a medical device for use as a wound dressing.

Claims 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al (WO 02/10221) as applied to claims 1-3, 8-11, 13, 14, 16, 20, 23, 24 and 29-33 above, and further in view of Hutcheon et al (US 5,807,295).

Applicant's arguments filed August 1, 2006 have been fully considered but they are not persuasive. Applicant's only argument is that Zamora is not an effective 103(a) reference. As noted above, it is a proper 102(a) reference and is therefore also a proper reference under 103(a).

Zamora teaches as set forth above. The reference does not teach the use of ethyl vinyl acetate, a dressing comprising an absorbent layer or a perforated polymeric film.

The preparation of would dressings is well known in the art. Hutcheon teaches a multi-layered wound dressing comprising a perforated polymeric (ethylene vinyl acetate) film to be placed in contact with the wound. See col 7, lines 1-14 and Fig. 4. The dressing further comprises an absorbent layer to collect wound exudates. The reference further suggests the use of absorbents such as chitosan as filler and the addition of pharmaceutically active agents. See col 3, lines 38-46

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the coated film product of Zamora for use in any known wound dressing preparation, such as the one taught by Hutcheon with a reasonable expectation of success. One of ordinary skill would be motivated to make such a modification because the Zamora product has utility for the preparation of a wound dressing and incorporates a bioactive/therapeutic agent, and this is expressly suggested by Hutcheon.

Double Patenting

Claims 1-7, 12, 21, 22, 25-28 and 34-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-29 of U.S. Patent No. 6,921,811. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '811 (10-21) are drawn to a medical device with a surface contacting bodily fluids coated with the same compound as Formula I in instant claim 4. It would be obvious to one of ordinary skill to select any of the claimed devices, one of which is a graft, which is a sub-genus of "wound dressing." Regarding claims 21 and 22, it would be within the scope of the artisan to optimize the value of these variables through routine experimentation. Claims 21-29 are drawn to the preparation of these devices. Regarding claims 27 and 28, the claims do not include the attachment of a second bioactive molecule, such as an antibiotic. However, it would be within the scope of the artisan to add and additional bioactive molecule for the combined effects. Regarding antibiotics, the specification expressly describes an antibiotic as a preferred bioactive molecule. The claims do not recite a method of use. However, the use of the particularly claimed medical devices would be obvious to one of ordinary skill.

Claims 1-7, 12, 21, 22, 25-28 and 34-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-37 of U.S. Patent No. 6,342,591. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '591 (11-21) are drawn to a medical device with a surface contacting bodily fluids coated with the same compound as Formula I in instant claim 4 but more narrowly claimed in terms of the bioactive molecule that is attached. It would be obvious to one of ordinary skill to select any of the described devices, such as "wound healing devices." See col 14, lines 35-45. The instant claims would be obvious over the claims of '591 for reasons set forth above.

Applicant states that a terminal disclaimer has been submitted to overcome these rejections. However, no terminal disclaimers appear to be with the submission filed August 1, 2006. It is noted that the "Electronic Acknowledgement Receipt" indicates that there was one 12-page document filed. The document is described as "Applicant Arguments/Remarks Made in an Amendment." The claims and remarks appear to account for the 12 pages. Furthermore, no fee for a terminal disclaimer has been charged.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
November 28, 2006